



K013171

JAN 03 2002

BCI, Inc.
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Summary of Safety and Effectiveness

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| Submitter: | BCI, Inc. |
| Address: | N7 W22025 Johnson Road Waukesha, WI 53186 |
| Telephone: | (262) 542-3100 |
| Contact: | VP Regulatory Affairs |
| Prepared: | September 21, 2001 |
| Proprietary Name: | BCI® 3420 Digit™ Pulse Oximeter |
| Common/Classification Name: | Pulse Oximeter |
| Predicate Devices: | BCI 3301® Hand-Held Pulse Oximeter (K943404) BCI® 3401 Handheld Pulse Oximeter (K980714) Nonin® Onyx , Model 9500 (K942248, K001085) |

New Device Description:

The BCI® 3420 Digit™ Pulse Oximeter consists of an pulse oximeter monitor and sensor contained on a single assembly. The device includes an LED display and power on key, and is powered by two "AAA" batteries.

Intended Use:

The BCI® 3420 Digit™ Pulse Oximeter is a handheld, finger-mounted pulse oximeter that combines the monitor and sensor into one assembly that measures SpO₂, pulse rate, and pulse strength. It may be used as a spot check device in the home, hospital or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings. The BCI® 3420 Digit™ Pulse Oximeter will provide reliable measurements on patients ranging from pediatric to adults.

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Performance Data:

The design of this device utilizes currently available technology found in legally marketed devices. The major difference between the new device and the predicate BCI 3301 Handheld Pulse Oximeter is the combination of the pulse oximeter monitor and sensor, similar to the Nonin® Onyx®. Testing was done to ensure that the BCI® 3420 Digit™ Pulse Oximeter would perform safely and accurately within the environment(s) for which it is to be marketed.

Safety and environmental testing was conducted in accordance with the *Reviewer's Guidance for Respiratory Devices*, 1993, EN 60601-1: 1990, and EN 60601-1-2: 1993. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing have been completed. The results demonstrate that the BCI® 3420 Digit™ pulse oximeter is in compliance with the guidelines and standards referenced in the reviewer's guides and that it performs within its specifications and functional requirements.

Testing of device performance included clinical testing of the SpO₂ parameter and overall software validation. The results demonstrated that the BCI® 3420 Digit™ pulse oximeter performed within its specifications.

The testing described above indicate that there is no functional difference between the operation of the BCI® 3420 Digit™ pulse oximeter and the predicate devices. Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

A handwritten signature in black ink, appearing to read "Donald Alexander", with a long horizontal flourish extending to the right.

Donald Alexander
VP Regulatory Affairs

BCI and Digit are a BCI trademarks. The symbol ® indicates it is registered in the U.S. Patent and Trademark Office and certain other countries. Nonin and Onyx are Nonin trademarks.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 03 2002

Donald J. Alexander
Vice President of Regulatory Affairs
BCI, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186-1856

Re: K013171
3420 Digit™ Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: November 20, 2001
Received: November 21, 2001

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

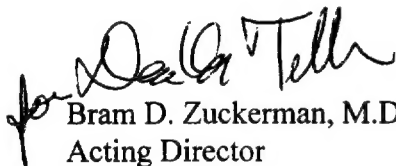
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K013171

Device Name: BCI® 3420 Digit™ Pulse Oximeter

Indications For Use:

Intended Use:

The BCI® 3420 Digit™ Pulse Oximeter is a handheld, finger-mounted pulse oximeter that combines the monitor and sensor into one assembly that measures SpO₂, pulse rate, and pulse strength. It may be used as a spot check device in the home, hospital or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings. The BCI 3420 Digit™ Pulse Oximeter will provide reliable measurements on patients ranging from pediatric to adults.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

[Signature]
Division of Cardiovascular & Respiratory Devices
510(k) Number K013171